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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1643

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04/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/521,723	Applicant(s) SHI ET AL.	
	Examiner Karen A. Canella	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20,44 and 46 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5,16-20,44 and 46 is/are rejected.
- 7) ☒ Claim(s) 6-15 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/19/2008</u> . | 6) <input type="checkbox"/> Other: ____. |

Art Unit: 1643

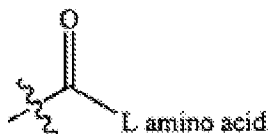
DETAILED ACTION

Claim 1 has been amended. Claims 1-20, 44 and 46 are pending and under consideration.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-20, 44 and 46 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the condition wherein R1a is H, X is NH, J is CH, Y is H, methyl or isopropyl, R2 is



and R1 is methyl and diagnostic agents comprising said compounds, does not reasonably provide enablement for the condition wherein R1a is H, X is NH, J is CH, Y is H, methyl or isopropyl, R2 is



and R1 is ethenyl or pharmaceutical composition comprising any of said compounds is withdrawn in light of applicant's amendment.

Claims 1-5, 16-20, 44 and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

Art Unit: 1643

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has amended claim 1 to obviate the rejection under 112, first paragraph for lack of enablement. However, neither of the originally filed disclosure nor the provisional application provide a written description of the genus of compounds encompassed by the instant claims wherein R1a is H, X is NH, J is CH, Y is H, methyl or isopropyl, R2 is



and R1 is methyl. The instant specification is consistent with only R1 being ethenyl in this case, and the provisional application fails to provide any of the proviso limitation, teaching only the motif of (V/T/I)-(P/A)-(F/Y/I/V) (page 9, line 2) which only partially describes the compounds of the instant claimed genus. Thus, one of skill in the art would reasonably conclude that applicant was not in possession of the proviso wherein R1a is H, X is NH, J is CH, Y is H, methyl or isopropyl, R2 is



and R1 is methyl. at the time of filing.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or

provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/395,918, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The '918 application does not provide an adequate written description of the instant claimed genus of compounds. The '918 application only partially describes the compounds of the instant claimed genus, such as compounds having the motif of (V/T/I)-(P/A)-(F/Y/I/V) (page 9, line 2). the '918 application makes no mention of the negative provisos of the instant claims, nor provides any written description in terms of structure

elements of the instant genus such as

The image displays several chemical structures representing different elements of a genus. At the top right is a polymer chain segment: $\text{---M---(CH}_2\text{---A)}_n\text{---}$. Below this, on the left, is a molecule with a central double bond connected to two wavy lines, with a wavy line also attached to one of the double-bonded carbons. To its right is a molecule with a central double bond connected to two wavy lines, with a hydroxyl group (OH) attached to one of the double-bonded carbons. Further right is a molecule with a central double bond connected to two wavy lines, with a hydroxyl group (OH) attached to one of the double-bonded carbons. Below these are two substituted benzene rings. The first is a benzene ring with substituents R^1 , R^2 , R^3 , and R^4 . The second is a benzene ring with substituents R^5 , R^6 , R^7 , and R^8 . The text "OR" is placed between the two benzene rings.

Thus, the '918 provisional application fails to support the instant claims. the earliest effective filing date commensurate with the instant claims is July 15, 2003.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

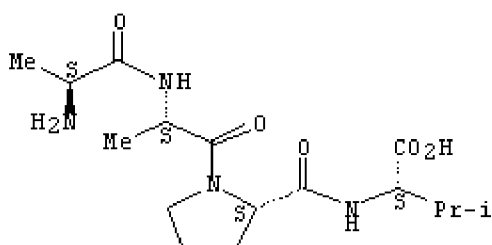
Art Unit: 1643

A person shall be entitled to a patent unless –

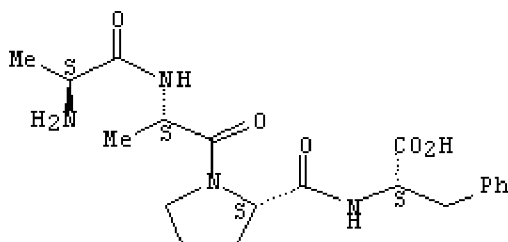
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 16-19, 44 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Meers et al (WO 98/16240).

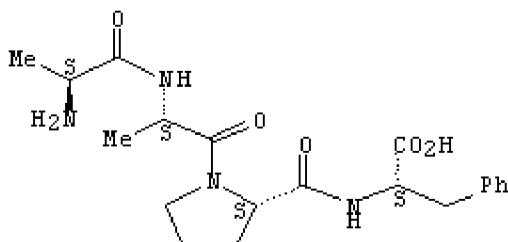
Meers et al disclose the tetrapeptides of AAPV:



AAPF:



and AAPM:



all of which meet the limitations of claims 1-4 and 16. AAPF meets the limitations of claims 17 and 18 because the R2a is benzyl and therefore the aralkyl of claim 17 which is not substituted and the benzyl of claim 19 which is not substituted. It is noted that neither of claims 17 or 19 require substitution of the aralkyl or a substituted benzyl as R2a.

Art Unit: 1643

Meers et al disclose pharmaceutical compositions comprising said peptides (page 14, first paragraph) which meets the limitation of claim 44 and compositions comprising the peptides and detectable agents (page 13, lines 13-15) which meets the limitation of claim 46.

Claims 1-5, 16, 17, 44, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Kipp et al (Biochemistry, June 2002, Vol. 41, pp. 7344-7349, reference of the IDS submitted November 19, 2008).

Kipp et al disclose the structure of AVPC-badan (page 7345, top right) which meets the limitations of 1-5, 16 and 17. Badan is a dye, therefor the limitations of claim 46 requiring a detectable from of the compound is met. Kipp et al also disclose the AVPI Tetrapeptide and Natural analogs (page 7347, top right) which also meet the limitations of claims 1-5 and 16. Kipp et al disclose that the tetrapeptides were reconstituted in water (page 7345, second column, last full paragraph), therefore the limitations of claim 46 are met.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

Art Unit: 1643

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 16-19 and 44 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,992,063. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims 1-6 and 12-14 of the patent anticipate the instant genus of compounds. Further claims 7-11 of the patent render obvious instant claim 44 because it would be obvious to make a pharmaceutical composition of the compounds of the patent in order to treat a mammal or human in need thereof.

Claims 1-5 and 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-32 of copending Application No. 10/777,946. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '946 application anticipate the instant claims to the extent that the molecule which binds to Iap is AVPC-badan (claims 10, 17, 26 of the '946 application) and thus has the structural limitations consistent with claims 2-5. Badan dye is a detectable label, therefore meeting the limitations of instant claim 46. Claims 18, 19, 30-32 of the '946 application are drawn to a method of treating cells or selectively damaging or killing neoplastic cells, there using a IAP-binding cargo. It would have been obvious to one of skill in the art to make a pharmaceutical composition comprising the Iap binding agent of AVPC as the Iap binding agent in order to administer to an individual in need thereof based on the teachings of claims 18, 19, 30-32 of the '946 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-5, 16-20, 44 and 46 are rejected.

Art Unit: 1643

Claims 6-15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/521,723

Page 9

Art Unit: 1643

/Karen A Canella/

Primary Examiner, Art Unit 1643